

## Communications | COVID-19 Impacts

In an effort to determine the impact of the COVID-19 pandemic on autologous and allogeneic hematopoietic cell transplantation practice, including outcomes, CIBMTR is requesting supplemental data for each qualifying transplant registered. This includes all allogeneic HCTs and research consented autologous HCTs. These data are essential to understanding how changes to the original transplant plan affect recipient outcomes. Impacts include changes to the original HCT date, donor, product type, preparative regimen, GVHD prophylaxis, and the need to cryopreserve the product. These data are expected to be used in future studies and reports, including the annual Center-Specific Survival Analysis (CSA) for HCT. The supplemental data will be collected prospectively, as long as the pandemic impacts how HCTs are performed. We are committed to ending the supplemental data collection at that time.

### Effective Tuesday, August 25<sup>th</sup>:

- Every Tuesday, COVID Impact Reports will be uploaded to the CIBMTR Portal for centers that have HCT qualifying events reported since March 1, 2020.
  - Primary data managers will be notified via email if their center has a report available in the CIBMTR Portal.
  - Centers should log into the CIBMTR Portal to download the COVID Impact Report. This report will be in the form of a spreadsheet.
  - Enter the supplemental data (see next section for specific data to be collected) for each CRID and return the completed file to [CIBMTR Center Support](#). Detailed directions can be found [here](#).
  - Once the completed file has been received, CIBMTR Center Support staff will review the data for accuracy and completeness.
  - If discrepancies are identified, CIBMTR Center Support staff will contact the center via the Center Support ticket process, to resolve all issues.
  - For each CRID, if no issues have been identified or once all discrepancies are resolved, the CRID will be removed from the COVID Impact Report and the ticket will be closed.

## Requested Supplemental Data (via spreadsheet in CIBMTR Portal)

### Question 1 – Was the HCT impacted for a reason related to the COVID-19 (SARS-CoV-2) pandemic?

Rationale: Capture baseline information on HCT impacts as related to the COVID-19 pandemic in instances of both allogeneic and autologous transplantation.

Response Options: Yes/No

### Question 2 – Original date of HCT (only completed when Q1 = Yes)

Rationale: Capture baseline information on HCT impacts as related to the COVID-19 pandemic.

- I. Provides an option for “date estimated” field for the original HCT date in case a specific date is not known.
- II. Provides a “no change planned” option for the original HCT date.

Response Options:

- I. Original date of HCT: Date
- II. Date estimated: Yes or Blank
- III. No change to planned HCT date due to COVID-19 pandemic: Yes or Blank

**Question 3 – Is the donor different than the originally intended donor? (only completed when Q1= Yes and Donor was ALLO)**

Rationale: Capture instances of allogeneic transplantation where donor source had to change due to the COVID-19 pandemic.

Response Options: Yes/No

**Question 4 – Specify the originally intended donor (only completed when Q3 = Yes and Donor was ALLO)**

Rationale: Capture original donor information in instances of allogeneic transplantation.

Response Options: Unrelated donor, Syngeneic, HLA-identical sibling, HLA-matched other relative, HLA-mismatched relative

**Question 5 – Is the product type (bone marrow, PBSC, cord blood unit) different than the originally intended product type? (only completed when Q1 = YES and Donor was ALLO)**

Rationale: Capture product type changes due to COVID-19 pandemic in instances of allogeneic transplantation.

Response Options: Yes/No

**Question 6 – Specify the originally intended product type (only completed when Q5 = Yes)**

Rationale: Capture original product type information

Response Options: Bone marrow, PBSC, CBU, Other product

**Question 7 – Specify other product type (only completed when Q6 = other)**

Rationale: Capture other product as reported in Q6.

Response Options: Free Text

**Question 8 – Was the current product thawed from a cryopreserved state prior to infusion? (only completed when Q5 = Yes)**

Rationale: Capture demand needs for cryopreserved product in allogeneic transplantation due to the COVID-19 pandemic.

Response Options: Yes/No

**Question 9 – Did the preparative regimen change from the original plan? (only completed when Q1= yes and Donor was ALLO)**

Rationale: Capture instances of preparative regimen changes due to the COVID-19 pandemic in instances of allogeneic transplantation. In this case, CIBMTR is just interested in whether the preparative regimen was altered, but not the specific details of the intended preparative regimen.

Response Options: Yes/No

**Question 10 – Did the GVHD prophylaxis change from the original plan? (only completed when Q1 = yes and Donor was ALLO)**

Rationale: Capture instances of Graft-versus Host Disease (GVHD) prophylaxis changes due to the COVID-19 pandemic in instances of allogeneic transplantation. In this case, the CIBMTR is just interested in whether the

GVHD prophylaxis was altered, but not specific details of the intended GVHD prophylaxis.

Response Options: Yes/No

## Frequently Asked Questions

### **Q: What qualifies as an “Impact”?**

**A:** Impacts include changes to the original HCT date, donor, product type, preparative regimen, GVHD prophylaxis, and the need to cryopreserve the product prior to shipment or after arrival at the Transplant Center.

### **Q: What if I can only find some of the data?**

**A:** Complete all fields for which information can be obtained. For any unknown fields, leave blank and use the excel feature to place a “comment/note” on the field describing why it was left blank (Right Click > New Comment). The spreadsheet will be reviewed for completeness and consistent formatting. A list may be returned to you if there is not sufficient detail to interpret your responses. Infusions will remain on your center’s weekly list until the data have been verified.

### **Q: What if our center cryopreserves all products (no matter the infusion type)?**

**A:** Cryopreservation is captured in Q22 on the HCT Infusion F2006 R5. Ensure this question is answered as “YES” on the F2006. On the COVID-19 Impact Spreadsheet, the intent is only to capture if the product was thawed from a cryopreserved state prior to transplant, due to the pandemic when it wouldn’t have otherwise been part of your process.

### **Q: What if our center postponed scheduling / admissions for transplants?**

**A:** Since the HCT plan was affected, this is considered an impact. It may be that only the date changed, but please answer all questions.

### **Q: What if this does not affect our annual volume of transplants?**

**A:** Although your annual volume may not have been affected, the intent of this data capture is to identify if the HCT plans have been impacted. CIBMTR requests that you report any impacts / changes to the HCT plan from your centers general protocol for each infusion due to the pandemic.

### **Q: What if the patient was infected with COVID-19?**

**A:** These supplemental questions are intended to capture the general impact of the pandemic on the patient’s treatment plan. There are questions on CIBMTR data collection forms that will ask if the patient was infected with the virus. If the course of treatment changed from your center’s general protocol, regardless of whether the patient contracted the virus, report those changes as an impact to HCT.

### **Q: What if patient deferred and wanted to wait to schedule?**

**A:** If the patient deferred due to the pandemic, this is considered an impact to HCT.

### **Q: What if donor wanted to wait to donate?**

**A:** This would be considered an impact, as this essentially could change the intended transplant date, the donor, or product type.

### **Q: What if our center cannot locate the data being requested?**

**A:** Please work with your center’s Medical Director, Transplant Coordinator, or Primary Care Physician to determine what impacts exist.

### **Q: What if our center does not have the capacity for this data collection? What are the consequences of non-compliance?**

**A:** These data will be used within the CIBMTR’s annual Transplant Center Specific Analysis report. Incomplete

data may prevent a patient from being included in the analysis for your center. A significant portion of missing data could cause your entire center to be excluded from the analysis.

**Q: What if our center does not know what the original transplant date would have been?**

**A:** We ask, that if able, to provide an estimated date. Use the general guidelines provided in the [forms instruction manual](#). An example: If the patient was seen the physician for their pre work- up on August 10<sup>th</sup>, and your centers general protocol was to schedule the HCT for 3-5 weeks later, then the estimated date would be September 1<sup>st</sup>. Since September 15<sup>th</sup> did not make logical sense, as it was not within the preferred timeframe, the 1<sup>st</sup> of the month was selected.

**If you have any questions or concerns, please contact CIBMTR Center Support (<https://nmdp.service-now.com/csm>)**